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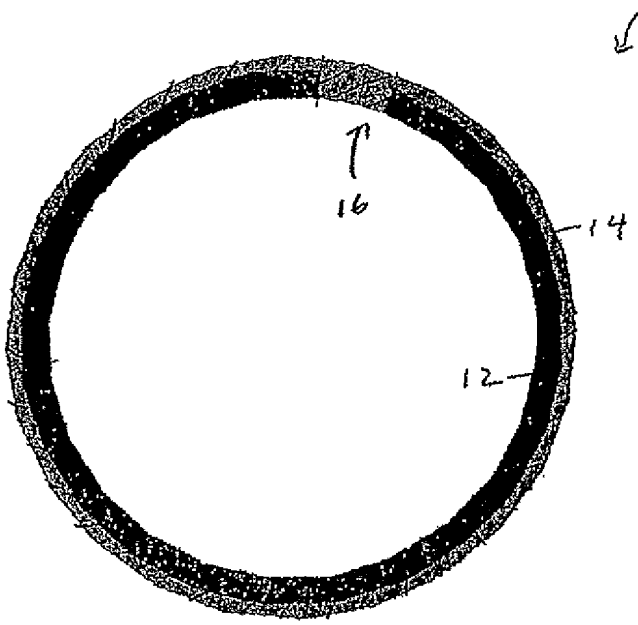
(54) Title: EXPANDABLE SHEATH TUBING



(57) Abstract: An introducer sheath or catheter can be formed in two or more layers with an inner layer made of a higher durometer material and an outer layer made of a lowerdurometer material. The inner layer can have one or a combination of the following: one or more longitudinal slits, overlapping portions, monolithic hinges, or other formations to allow for radial expansion.

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EXPANDABLE SHEATH TUBING

Cross-reference to Related Application

This application claims priority to provisional application no. 60/421,436, filed October 25, 2002, which is incorporated herein by reference.

Background of the Invention

In many minimally invasive cardiac procedures, an introducer sheath may be placed in a vessel to gain access to a surgical site. Sheaths are used as conduits to pass surgical instruments or implantable devices through them. It is generally desirable to minimize the outer diameter of the sheath and maximize the inner diameter of the sheath. A small outer diameter is desired to minimally disrupt the circulatory pathway and is sometimes based on the anatomical size of the vessel it is designed to access. The inner diameter is designed as necessary for the surgical instrument or implant device to pass through it. An example of a catheter shown with a "daisy occluder" folded down for delivery within the catheter is shown in U.S. Patent No. 5,741,297.]

Summary of the Invention

A sheath can be formed in two or more layers with an inner layer made of a higher durometer (more rigid), less elastic material and an outer layer made of a lower durometer (softer), more elastic material. The inner layer can have one or a combination of the following: one or more longitudinal slits, overlapping circumferential portions, monolithic hinges, or other formations to allow for radial expansion. These formations can be present along a portion or the entire length of the sheath. Other materials can be added to the sheath, such as wires for strength, or the device can be made to have a minimal number of parts and portions.

The sheath can be an introducer sheath through which a guide wire and catheter are inserted, or the sheath can be a catheter or any other tubing inserted into a living body and through which other devices pass, such as stents, filters, occluders, or other devices. The sheath can be made by coextruding the layers, or with a dipping process.

In another embodiment, two materials can be used such that the materials alternate in a circumferential direction between more rigid, less elastic sections and

softer, more elastic sections. In this case, the two materials can have the same wall thicknesses throughout the length of the sheath.

A radially expandable sheath allows a device to pass through a smaller diameter sheath than the device would otherwise be able, and thereby in a less invasive fashion. The sheath can be made smaller than the diameter of the device (at its maximum cross-section), so that the sheath expands slightly as the device passes through. With a brief radial expansion of the sheath, the trauma to the vessel through which it passes should be minimal. An expandable sheath can also be useful in retrieving a device from a body if the device, as folded for retrieval, has a larger diameter than it had when it was introduced into the body. Other features and advantages will become apparent from the drawings and detailed description.

Brief Description of the Drawings

Figs. 1-6 are cross-sectional views of a conduit according to various embodiments of the present invention.

Fig. 7 has a series of partial cross-sectional, partial side views of a catheter with an occluder for delivery and for retrieval.

Detailed Description

In the embodiments of Figs. 1-5, a relatively soft (lower durometer), more elastic outer material and a relatively rigid (higher durometer), less elastic inner material are coaxial, and preferably extruded, to form a tubular sheath that can expand radially, preferably for brief periods while a device is passed through, while not allowing significant longitudinal expansion. This capability allows a smaller diameter sheath to be used to deliver a device with a larger diameter, or allows a retrievable device to be withdrawn more easily if the device, in its retrieved state, has a larger diameter than in its delivered state, in each case while minimizing vessel occlusion. It is desirable for the vessel not to be enlarged, or if it does have to be enlarged, for it to happen for a minimal amount of time to allow the vessel to recover. The coextrusion of similar materials of differing durometer allows the inner layer and outer layer to bond thermally without significant delamination. Dissimilar materials could form a thermal bond or could be bonded through an intermediate layer. The more rigid material that makes up the inner layer can have one or more lengthwise slits filled in

whole or in part with the softer material from the outer layer. The outer layer is entirely made of the softer material.

The layers should each be made of extrudable materials, such as polyether-block co-polyamide polymers, such as resins sold under the Pebax® name. Other combinations of materials for coextrusion can be used, such as a high density polyethylene for the rigid material, and a styrene-ethylene-butadiene block copolymer for the soft segment (such as C-Flex® or Kraton®). Other useful materials include silicone, polytetrafluoroethylene (PTFE), perfluoro (ethylene-propylene) copolymer (FEP), or urethane. It is generally desirable for the selected materials to melt together during the coextrusion process to prevent delamination. While many materials can be used, exemplary ranges for durometer on a Rockwell scale are 20-70 on the A scale for the outer material, and 60-80 on the D scale for the inner material. These ranges are only examples, and materials with other durometers could be used; for example, the material referred to as C-Flex is commercially offered in custom form with a durometer of 5-95A.

Referring to Fig. 1, a sheath 10 has an inner layer 12 made of a relatively rigid material and an outer layer 14 made of a relatively soft material. Inner layer 12 has a longitudinal slit 16. During the coextrusion process, the softer material used to make outer layer 14 fills some or all of the gap created by slit 16. The slit provides some added flexibility for the inner layer. The device can be formed with one or more longitudinal slits that can extend for some or all of the length of the sheath.

In one embodiment, an inner layer is made of extruded Pebax 7233 with inner diameter 0.150" (3.8 mm) and outer diameter 0.166" (4.2 mm). The wall has a 0.023" (0.58 mm) wide lengthwise channel and it is overcoated with a softer extruded Pebax 2533 with outer diameter 0.174" (4.4 mm).

Referring to Fig. 2, a sheath 20 has an inner layer 22 and an outer layer 24. As with the sheath of Fig. 1 and the others described herein, the inner layer is made of a more rigid, higher durometer, less elastic material, while the outer layer is made of a softer, lower durometer, more elastic material. As shown here, inner layer 22 has an overlapping region 26 that provides some flexibility for inner layer 22 to expand. The softer outer layer 24 provides elasticity to allow some radial expansion. In other words, the inner layer is made of a less elastic material but has a formation to assist in its ability to expand radially, while the outer layer is made of a more elastic material.

Referring to Fig. 3, sheath 30 has an inner layer 32, an outer layer 34, and a hinge 36. Hinge 36 is integral, and preferably monolithic, with respect to inner layer 32, and has symmetric curved portions that allow layer 32 to expand and allow hinge 36 to pivot about a pivot point 38 to expand the diameter.

Referring to Fig. 4, a sheath 40 has an inner layer 42, an outer layer 44, and four integral, and preferably monolithic, hinges 46A-46D, each of which can allow inner layer 42 to expand radially. While four of these hinges are shown in Fig. 4, there could be two or more, and they could be evenly spaced about the circumference of inner layer 42 or spaced at irregular intervals as desired.

Referring to Fig. 5, an outer layer 54 surrounds an inner layer 52 which has reduced thickness portions 56 and greater thickness portions 58 spaced about the inner circumference of inner layer 52, thereby allowing layer 52 to expand. Four such greater thickness portions are shown, but there could be more or fewer.

In these embodiments described above, the inner layer typically has some geometric construction or formation, such as the use of a slit, overlapping portion, varying thickness, hinge, or other structure that gives the stiffer and less elastic inner layer more ability to expand radially than it otherwise would have. The outer layer is made of a softer and more elastic material, and therefore does not have as much need to have such geometric formations that assist in the expansion, although the outer layer could have some other formation and not necessarily be substantially just cylindrical as shown.

The sheaths described here are particularly useful for providing a conduit for other devices, such as stents, occluders, or guide wires, to be inserted into a human or non-human animal body. As is generally known, it is desirable for such a sheath to have as small a diameter as possible to minimize trauma to the vessel into which it is inserted. In the event some expansion to the vessel is required, it is desirable for it to be radial and short-term only to allow the vessel to recover its original shape.

A sheath as described herein can be used with a device that is small enough to fit through the sheath without expanding the sheath, but which, if it is necessary to be retrieved, has a larger diameter (at least in some parts) on retrieval. Referring to Fig. 7, for example, a device, such as a patent foramen ovale (PFO) closure device or an occluder can have two connected hubs, each with radial spokes for supporting a fabric. This device has an appearance of two umbrellas, each concave and facing the other. For delivery, each of the "umbrellas" may be folded down separately within

the catheter. These sides open up on distal and proximal deployment on opposite sides of a PFO or occlusion. If retrieved, the closure device may be folded in a configuration different from that in which it was delivered, e.g., such that the arms are bent back and the umbrellas overlap. Consequently, the cross-sectional diameter of the retrieved device passing through the conduit would be greater than the delivered device at some points. With the conduit of the present invention, the device could be delivered through the conduit without any expansion, but if retrieval is necessary during the procedure, the conduit can allow some temporary expansion for the device to pass through during retrieval. The conduit could also expand for both delivery and retrieval.

Many different diameters and thicknesses can be used to get the desired specifications for a particular application. Additional configurations of this embodiment may include longitudinal support structures such as wires that can be extruded as part of the inner and/or outer layers over all or part of the length of the layer. Wires can improve kink resistance while still enabling radial expansion of the tube.

A coating could be added to the inside and/or outside of the layers, such as a hydrophilic coating on the outer surface of the outer layer to assist with passage through the body if the outer layer is tacky. The lubricity provided by the coating can reduce the resistance to the device being pushed through the sheath.

While additional materials, such as longitudinal support wires, can be added, the sheath can be limited primarily to inner and outer layers, preferably coextruded, for use of fewer parts and steps and for ease of manufacture.

Another embodiment is shown in Fig. 6. As shown here, a sheath 60 has relatively rigid and less elastic sections 62 and 64, and relatively soft and more elastic sections 66 and 68, which essentially form stripes of soft material. In this case, the wall thickness can be substantially uniform, but with different materials in a circumferential direction. While two sectors each of rigid and soft are shown, more sectors could be provided, including one or more with still different durometer from the other two sectors. Like the embodiments of Figs. 1-5, the conduit in this embodiment could temporarily expand as a device is passed through when delivered and/or retrieved.

The present invention thus includes designs for an expandable sheath, such as an introducer sheath or a catheter, that is inserted into a body, such as a human body;

methods for making an expandable sheath, including coextrusion and dipping, to provide a sheath with radial flexibility; uses of such sheaths, such as for insertion into a body, such as a human body, to assist in delivering and/or retrieving a device, such as a stent, blood clot filter, or occluder, with at least a portion having a diameter greater than the inner diameter of the sheath when both are outside the body; and combinations of sheaths and devices as indicated above, including the combination of a sheath with a first inner diameter, and a device for passage through the sheath with at least a portion having a second diameter greater than the first diameter.

Accordingly, the present invention has been described with respect to exemplary embodiments of the present invention. It should be appreciated, though, that the present invention is defined by the following claims. Modifications or changes may be made to the exemplary embodiments of the present invention without departing from the inventive concepts contained herein or the scope of the claims.

What is claimed:

CLAIMS

1. A device comprising:

a conduit for insertion into a living body, and through which another device passes, the conduit having inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer, wherein the durometer of the inner layer is greater than the durometer of the outer layer.

2. The device of claim 1, wherein the conduit is an introducer sheath.

3. The device of claim 1, wherein the conduit is a catheter.

4. The device of claim 1, wherein the inner layer has means for assisting the diameter of the inner layer to expand.

5. The device of claim 4, wherein the assisting means includes a slit formed longitudinally in the inner layer.

6. The device of claim 4, wherein the assisting means includes a circumferentially overlapping portion.

7. The device of claim 4, wherein the assisting means includes a hinge portion.

8. The device of claim 7, wherein the hinge is monolithic with the inner layer.

9. The device of claim 8, further comprising a plurality of monolithic hinge portions.

10. The device of claim 7, wherein the assisting means includes reduced and greater thickness portions.

11. The device of claim 10, further comprising a plurality of reduced and greater thickness portions.

12. The device of claim 4, wherein the assisting means includes one or more geometric formations that aid in expansion.

13. The device of claim 1, wherein the inner layer has a durometer in a range of 60-80 on the D scale.

14. The device of claim 13, wherein the outer layer has a durometer in a range of 20-70 on the A scale.

15. The device of claim 1, wherein the outer layer has a durometer in a range of 20-70 on the A scale.

16. The device of claim 1, further comprising a medical device for insertion through the conduit, the medical device having a portion with an outer diameter greater than the inner diameter of the inner layer, the conduit expanding temporarily and radially as the medical device is passed through.

17. The device of claim 16, wherein the medical device is selected from the group consisting of a stent, blood clot filter, or occluder.

18. The device of claim 1, further comprising a medical device for passing through the conduit,

the medical device being foldable in a first manner for delivery through the conduit and in a second manner different from the first manner for retrieval,

the cross-section of the device as folded in the second manner being greater than the cross-section of the device as folded in the first manner, the device as folded in the first manner having an outer diameter less than the inner diameter of the conduit, the device as folded in the second manner having an outer diameter greater than the inner diameter of the conduit, the conduit not expanding as the device is delivered and expanding temporarily and radially as the medical device is retrieved.

19. A device comprising a conduit for insertion into a living body, and through which another device passes, the conduit having inner and outer coaxial layers such that the outer layer surrounds the inner layer, wherein the elasticity of the material used to form the outer layer is greater than the elasticity of the material to form the inner layer, the inner layer having a geometric formation for assisting the radial expansion of the inner layer.

20. The device of claim 19, wherein the conduit is an introducer sheath.

21. The device of claim 19, wherein the conduit is a catheter.

22. The device of claim 19, wherein the geometric formation includes one or more of the following: a slit formed longitudinally in the inner layer, a circumferentially overlapping portion, a hinge portion, a hinge, a monolithic hinge, a plurality of hinges, a reduced and greater thickness portion, a plurality of reduced and greater thickness portions.

23. The device of claim 19, further comprising a medical device for insertion through the conduit, the medical device having a portion with an outer diameter greater than the inner diameter of the inner layer, the conduit expanding temporarily and radially as the medical device is passed through.

24. The device of claim 23, wherein the medical device is selected from the group consisting of a stent, blood clot filter, or occluder.

25. The device of claim 19, further comprising a medical device for passing through the conduit,

the medical device being foldable in a first manner for delivery through the conduit and in a second manner different from the first manner for retrieval,

the cross-section of the device as folded in the second manner being greater than the cross-section of the device as folded in the first manner, the device as folded in the first manner having an outer diameter less than the inner diameter of the conduit, the device as folded in the second manner having an outer diameter greater than the inner diameter of the conduit, the conduit not expanding as the device is delivered and expanding temporarily and radially as the medical device is retrieved.

26. A method comprising:

forming one of an introducer sheath or catheter through which a medical device is passed with inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer, wherein the elasticity of the inner layer is greater than the elasticity of the outer layer.

27. The method of claim 26, wherein the layers are bonded together through co-extrusion.

28. The method of claim 26, wherein the layers are bonded together through dipping.

29. The method of claim 26, further comprising forming the inner layer with means for allowing the diameter of the inner layer to expand.

30. The method of claim 26, wherein the forming includes forming an introducer sheath.

31. The method of claim 26, wherein the forming includes forming a catheter.

32. A method comprising:

providing a medical device through a conduit in a living body, the conduit having inner and outer coaxial layers bonded together such that the outer layer surrounds the inner layer, the elasticity of the inner layer being greater than the elasticity of the outer layer, the conduit temporarily expanding in the radial direction as the device passes through.

33. The method of claim 32, wherein the medical device has an outer diameter greater than the inner diameter of the inner layer.

34. The method of claim 33, wherein the outer diameter of the device is greater when it is delivered.

35. The method of claim 33, wherein the outer diameter of the device is greater when it is retrieved, but not when it is delivered.

36. The device of claim 32, wherein the medical device is selected from the group consisting of a stent, blood clot filter, or occluder.

37. The method of claim 32, wherein the inner layer has means for assisting the inner layer to expand radially.

38. A device comprising:

a conduit for insertion into a living body, and through which another device passes, the conduit having first and second types of sections in a circumferential direction, wherein the elasticity of one type of section is greater than the elasticity of

the other type of section, the different elastic sections allowing the conduit to expand temporarily in the radial direction.

39. The device of claim 38, further comprising a medical device for insertion through the conduit, the medical device having a portion with an outer diameter greater than the inner diameter of the inner layer, the conduit expanding temporarily and radially as the medical device is passed through.

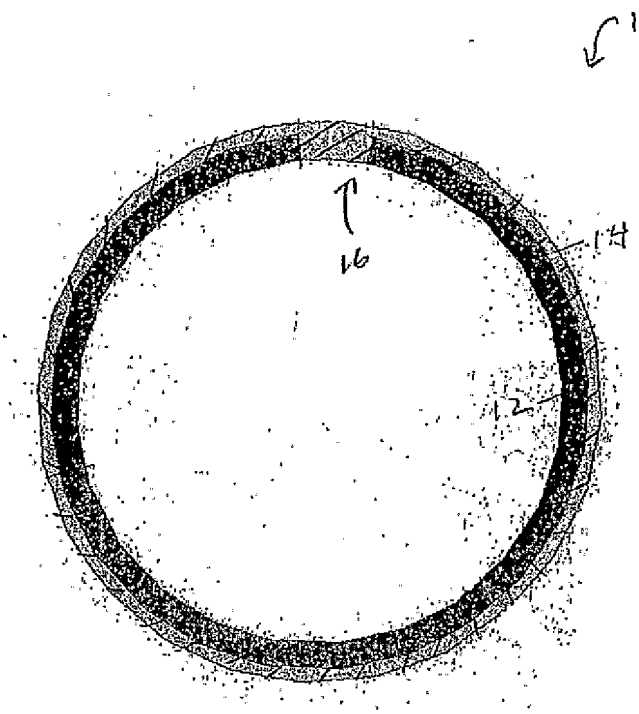
40. The device of claim 39, wherein the medical device is selected from the group consisting of a stent, blood clot filter, or occluder.

41. The device of claim 38, further comprising a medical device for passing through the conduit,

the medical device being foldable in a first manner for delivery through the conduit and in a second manner different from the first manner for retrieval,

the cross-section of the device as folded in the second manner being greater than the cross-section of the device as folded in the first manner, the device as folded in the first manner having an outer diameter less than the inner diameter of the conduit, the device as folded in the second manner having an outer diameter greater than the inner diameter of the conduit, the conduit not expanding as the device is delivered and expanding temporarily and radially as the medical device is retrieved.

42. The device of claim 38, wherein the conduit has a substantially uniform wall thickness.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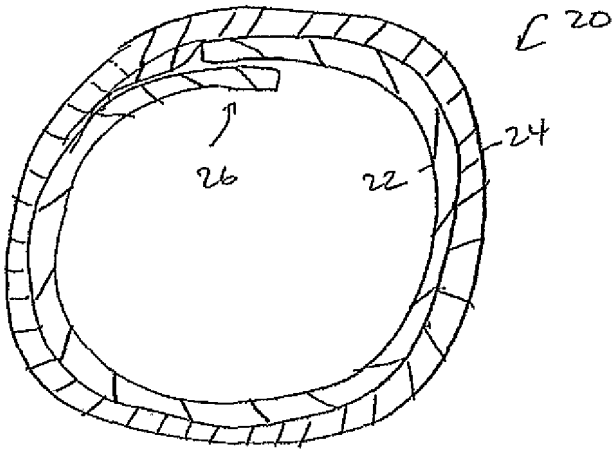

FIG-2

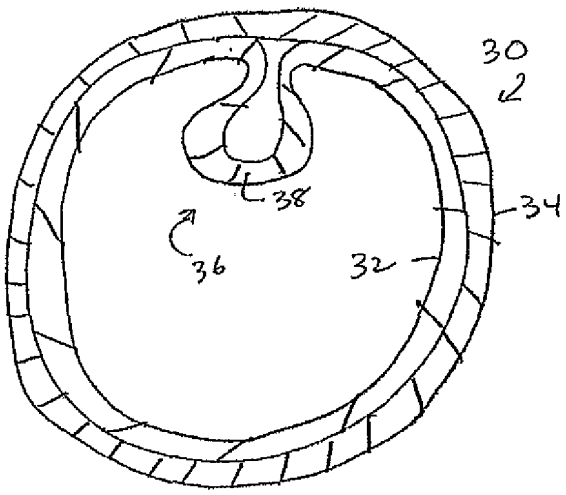

FIG-3

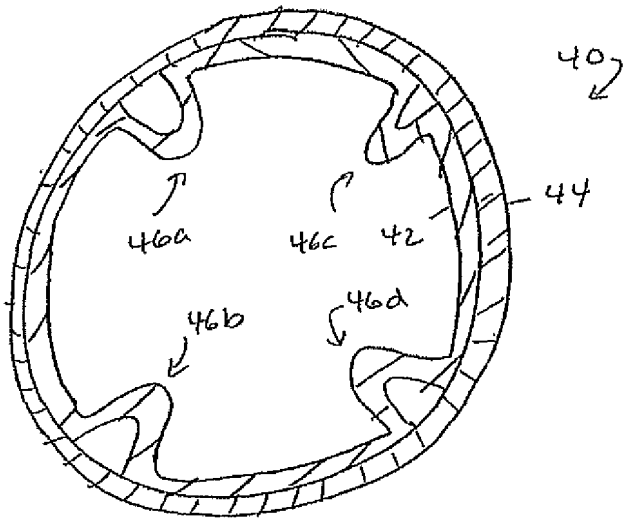

FIG. 4

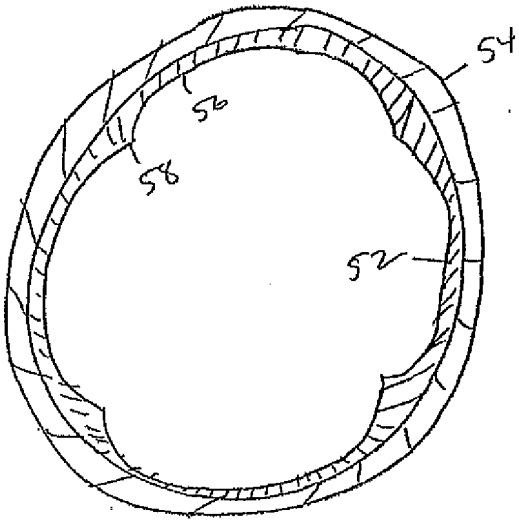

Fig. 5

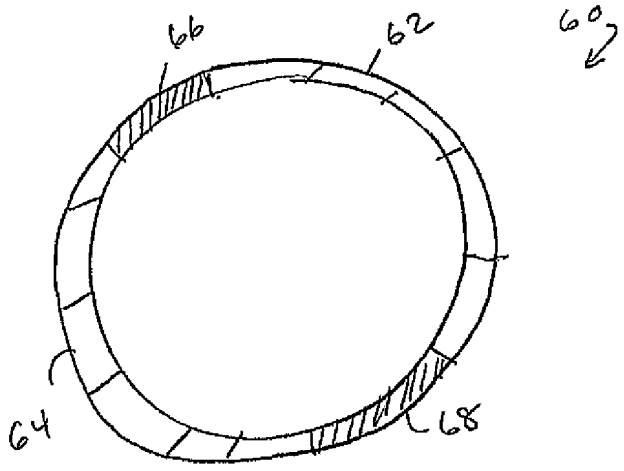

FIG. 6

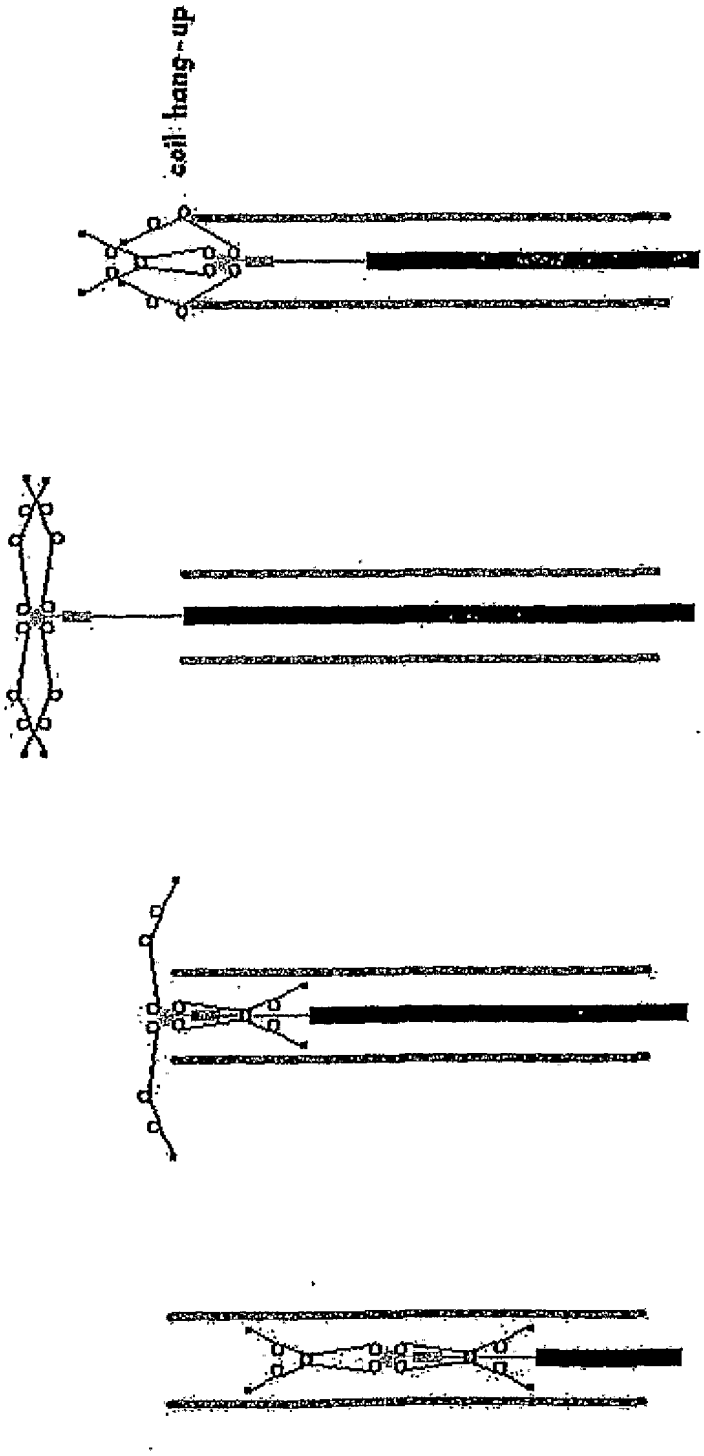
coil hang-up
1. Delivery
2. Distal Deployment
3. Proximal Deployment
4. Occluder Recovery
arms bent back
whole system removed

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/34003

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/06 A61M25/00 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/032459 A1 (HORZEWSKI ET AL.) 14 March 2002 (2002-03-14) abstract; figures paragraphs '0045!, '0047!, '0053!, '0054!	1-8,10, 12-26, 29-31
X	EP 0 839 549 A (CORDIS CORPORATION) 6 May 1998 (1998-05-06) the whole document	38-42
X	WO 98/29026 A (IMAGYN MEDICAL TECHNOLOGIES, INC.) 9 July 1998 (1998-07-09) abstract; figures page 8, lines 9-16	1-5, 12-26, 29-31

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 March 2004	10/03/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Giménez Burgos, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/34003

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 840 623 A (QUACKENBUSH) 20 June 1989 (1989-06-20) the whole document	1-4, 7-27, 29-31

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/34003

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 32-37
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/34003

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